



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,512	05/01/2001	Rachel Meyers	MPI00-185P1R2RCM	5523

7590

09/07/2005

INTELLECTUAL PROPERTY GROUP
MILLENNIUM PHARMACEUTICALS INC
40 LANDSDOWNE STREET
CAMBRIDGE, MA 02139

EXAMINER

YU, MISOOK

ART UNIT PAPER NUMBER

1642

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/846,512

Applicant(s)

MEYERS ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 83-104 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 94-104 is/are allowed.
6) ☒ Claim(s) 83-87, 89-91, 93 is/are rejected.
7) ☒ Claim(s) 88 and 92 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 83-104 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found.

Claim Rejections - 35 USC § 112, Withdrawn

The rejection of claims 83-93, and 95 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn upon review of the specification in light of applicant's argument.

Claim Rejections - 35 USC § 102, maintained

Claims 83-87, 89-91, and 93 remain rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. 6,294,663 (the '663 patent, issue, filed 02 March 2000).

Claims 83-87, 89-91, and 93 have two-part active steps, i.e. contacting SEQ ID NO: 2 protein with a compound (as listed in claims 87, and 89) and determine whether the compound interacts with the protein, wherein the interaction is determined by the various art-known method listed in claim 93.

Applicant argues that the claimed methods of the instant application and those in the '663 patent are in fact very different, in that the '663 patent does not teach each and every element of the pending claims, specifically, the methods taught by the '663 patent are directed to detecting expression of a TADG-12 protein, diagnosing a cancer or other malignant hyperplasia, inhibiting expression of endogenous TADG-12, targeted therapy, and vaccinating an individual against TADG-12, whereas the recited in the claims of the present application are directed to identifying a compound capable of interacting with a

Art Unit: 1642

14094 polypeptide. The '663 patent does not mention, describe or even seem to contemplate such a method.

These arguments have been fully considered but found unpersuasive because the '663 patent discloses a protein sequence (i.e. SEQ ID NO: 2) that is at least 95 % identical to instant SEQ ID NO: 2 (note previously provided Exhibit A, attached with the Office action mailed on 04/01/2005). As for the screening for a compound interacting with at least 95 % identical to the instant SEQ ID NO: 2, the patent at the paragraph bridging columns 11 and 12 teaches that the disclosed protein (i.e., at least 95 % identical to instant SEQ ID NO: 2) is used to "test existing antibodies". This statement is same as the instantly claims 83, and 87 as concurrently construed. Only different is semantic difference, i.e. the instant claims say identifying a candidate compound" but the patent say "test existing antibodies". As for the actual testing of interacting, note the immunohistochemistry assay as shown at Fig. 7 of the patent.

As for other limitations in the claims, the patent teaches that the disclosed invention is TADG-12 protein, which is at least 95% identical to the amino acid sequence of the instant SEQ ID NO: 2. The patent teaches that TADG-12 protein is most likely a receptor expressed at the surface because it contains LDL receptor like domain, scavenger receptor cysteine rich domain, transmembrane domain, and a serine protease domain. The patent teaches that since the protein is overexpressed in ovarian cancer, it may be used as a molecular target for therapy, and further teaches receptor assay, in which the material to be assayed is appropriately labeled and then certain cellular test colonies are inoculated with a quantity of both the label after which

Art Unit: 1642

binds to the cell receptors. In this way, differences in affinity between materials can be ascertained. Note column 8 lines 43 to column 9 line 21. As for claim 89, the broadly claimed "a member of a biological library" reads on "the material to be assayed" at lines 63 and 64 of column 8.

Allowable Subject Matter

Claims 94-104 are allowed.

The objected claims are objected because they depend on the rejected base claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

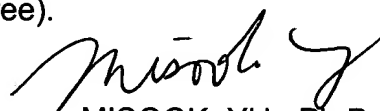
Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-

Art Unit: 1642

272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MISOOK YU, Ph.D.
Examiner
Art Unit 1642